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Early versus late laparoscopic cholecystectomy in acute biliary pancreatitis: a prospective randomised study

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ABSTRACT

Background: In patients with acute biliary pancreatitis, cholecystectomy is mandatory to prevent further biliary events, but the precise timing of cholecystectomy for mild to moderate disease remain a subject of ongoing debate. The aim of this study is to assess the outcomes of early versus delayed cholecystectomy. We hypothesize that early cholecystectomy as compared to delayed cholecystectomy reduces recurrent biliary events without a higher peri-operative complication rate.

Methods: Patients with mild to moderate ABP were prospectively randomized to either an early cholecystectomy versus a delayed cholecystectomy group. Recurrent biliary events, peri-operative complications, conversion rate, length of surgery and total hospital length of stay between the two groups were evaluated.

Results: A total of 70 patients were enrolled at tertiary care hospital in central India. Of them, 35 were randomized to the early group and 35 patients to the delayed group using simple randomization technique.

Conclusions: In mild to moderate ABP, early laparoscopic cholecystectomy reduces the risk of recurrent biliary events without an increase in operative difficulty or perioperative morbidity.

Keywords: Laparoscopic cholecystectomy, Hot cholecystectomy, Acute biliary pancreatitis, Delayed cholecystectomy, Biliary events

INTRODUCTION

Acute pancreatitis is an inflammatory disease of the pancreas. The incidence of alcoholic pancreatitis is higher in male, and the risk of developing acute pancreatitis in patients with gallstones is greater in male. However, more women develop this disorder since gallstones occur with increased frequency in women.¹ Acute pancreatitis (AP) can be initiated by several factors, including gallstones, alcohol, trauma, infections and hereditary factors. About 80% of pancreatitis is caused by gallstones or alcohol.²

The underlying reason of gallstone disease and other conditions causing acute pancreatitis is ductal hypertension resulting from ongoing exocrine secretion into an obstructed pancreatic duct. Elevated intraductal pressure, due to ongoing exocrine secretion, causes rupture of the smaller ductuli and leakage of pancreatic juice into the parenchyma. Gallstone disease is the leading cause of acute pancreatitis in developed nations, accounting for up to 75% of cases. In Malaysia, a retrospective study done over a period of 7 years showed that in nearly one-half of the patients (45.1%) admitted for acute pancreatitis, the etiology was biliary calculi,

followed by alcohol intake.³⁻⁵ After biliary pancreatitis (BP), patients may experience a recurrent episode of biliary pancreatitis, common bile duct (CBD) obstruction, cholangitis, or biliary colics. Cholecystectomy and clearance of stones from the biliary tree remain the mainstay of treatment to prevent recurrent biliary events.⁶ Most cases of acute biliary pancreatitis (ABP) are mild and self-limiting; however, 10-20% of patients develop severe pancreatitis, which is associated with high morbidity and mortality.⁷

The timing of cholecystectomy in patients with clinically severe pancreatitis, with local complications such as pancreatic necrosis and organ failure, is deliberately delayed until local complications have resolved, typically after approximately 6 weeks. For mild to moderate ABP, international guidelines recommend early cholecystectomy. The International association of pancreatology (IAP) recommends that all patients with gallstone pancreatitis should undergo cholecystectomy as soon as the patient has recovered from the attacks, whereas the British society of gastroenterology recommend cholecystectomy within the same hospital admission or up to 2 weeks after discharge.⁸⁻¹⁰

Objectives

The objective of this study is to assess the benefits and harms of early versus delayed laparoscopic cholecystectomy (LC) in people with acute biliary pancreatitis.

METHODS

In the current study, all the patients admitted to Government medical college & hospital, Nagpur in central India, diagnosed to have mild to moderate acute biliary pancreatitis (ABP) who meet the inclusion criteria and gave informed consent to participate in the study were prospectively randomized to early and late group. This was a prospective type of randomized control study. A total of 70 patients were enrolled at tertiary care hospital in central India. Of them, 35 were randomized to the early group and 35 patients to the delayed group using simple randomization technique. The patients included in study were admitted from OPD as well as from emergency. The duration of the study was June 2019 to March 2022 prospectively. Primary outcome factor was recurrence of acute biliary events. Secondary outcome factors included operative time; conversion to open procedure, duration of hospital stay; perioperative complications, postoperative complications including fever, surgical site infections, chronic pain and other complications if any.

Inclusion criteria

Inclusion criteria for current study were; patient consenting to participate, newly admitted cases of mild to moderate acute biliary pancreatitis (ABP) presenting in

casualty & OPD and patient of acute biliary pancreatitis (ABP) undergoing LC in tertiary care Government medical college of Central India.

Exclusion criteria

Exclusion criteria for current study were; patient refusing to participate, patient not undergoing surgery, patient undergoing open cholecystectomy, severe pancreatitis (as defined by the presence of 3 or more of Ranson's criteria), severe preexisting medical comorbidity contraindicating cholecystectomy and pregnancy.

Patients satisfying the inclusion criteria were enrolled for the study. The diagnosis of ABP was based on clinical presentation as pain in abdomen sometimes radiating to back of the patient with or without jaundice sometimes associated with vomiting with detailed history regarding previous similar episodes and admissions and/or interventions like ERCP guided Stenting if any followed by laboratory and radiological investigations as above mentioned. Modified Ranson's criteria were used to decide the severity ABP as mild, moderate or severe. As mentioned earlier, the severe pancreatitis patients were excluded from this study. Once the diagnosis of mild to moderate ABP was made, all patients were subjected to preoperative evaluation including detailed history taking, clinical examination and basic laboratory investigations. All patients were subjected to further investigations as part of pre-anaesthetic work up including X-ray chest, ECG etc. Patients were divided into 2 groups; early & late group randomly by drawing a sealed, unlabeled, unordered envelope from a container by an independent party immediately after informed consent was obtained thus by simple random method. The early group underwent LC within 7 days of admission and the Late group was conserved to relieve the pancreatitis episode and called back on later date for Interval (6 weeks later)/ Late (>8 days after admission) LC. Necessary interventions like ERCP with Stenting as per the need on subjective basis in case of Choledocholithiasis and other indications were also done. Laparoscopic technique was used in all procedures. Intraoperative findings like choledocholithiasis or CBD stent etc. were noted. Operating time was calculated from port insertion to port removal. Postoperative antibiotics and analgesia given was same for both the groups. Routine administration of diclofenac injection was given postoperatively to each patient. Tablet diclofenac was given to all patients twice a day for 3 days. Pain score was assessed on 1st, 3rd, 7th, post-operative day using visual analogue scale other postoperative complications like bleeding, fever, soaking, pus discharge, chronic pain, jaundice was also noted. Return to normal activity was described as the patient's ability to perform basic elementary activities (i.e., getting dressed, walking) and home activities like (bathing, and performing daily household chores). On follow up visit complications involved were assessed. Patients were called up for follow up 1 month, 3 months, 6 months and 1 year after the operation to note the complications and

recurrence of biliary events or abdominal pain. Patients who could not come for a follow-up visit were contacted telephonically and the questionnaires were filled. Total duration of follow up was 2 years.

Statistical analysis

The sample size for this study was determined after analysing hospital database for acute biliary pancreatitis. All the data was collected and tabulated. Continuous variables were presented as Mean SD. Categorical variables were expressed in frequency and percentages. Categorical variables were compared by performing Chi-square test. For small numbers, Fisher exact test was used wherever applicable. Continuous variables were compared by performing independent t-test, $p < 0.05$ was considered as statistical significance. Statistical software STATA version 14.0 was used for data analysis

RESULTS

Age distribution

In the present study we observed that majority of the subjects belonged to the age group of 41 to 50 years (31.58% of early & 23.68% of late). The p value was statistically not significant. Gender distribution in present study it was seen that 63.16% of the early group were males and 36.84% were females. While, 68.42% of the late group were males and 31.58% were females. The p value on gender distribution comparing the two groups was 0.629 which was statistically not significant (Table 1).

Table 1: Age and gender based distribution of study population.

Variables	Early		Late	
	N	%	N	%
Age (years)				
11-20	2	5.26	3	7.89
21-30	6	15.79	4	10.53
31-40	10	26.32	4	10.53
41-50	12	31.58	9	23.68
51-60	2	5.26	8	21.05
61-70	2	5.26	5	13.16
>70	4	10.53	5	13.16
Total	38	100	38	100
Mean age \pm SD (range)	42.55 \pm 15.57 (14-76)		48.52 \pm 17.71 (13-84)	
Gender				
Male	24	63.16	26	68.42
Female	14	36.84	12	31.58

Clinical presentation of patient with acute biliary pancreatitis

We observed that all (100%) study subjects in both groups presented with right upper sided abdominal pain,

followed by Fever among 52.63% of early group & 23.66% of late group, nausea-vomiting, jaundice, clay-coloured stools were also assessed. The previous history of pain in abdomen was also noted which was found in 100% of Subjects from Late group while only 7.89% of the early group. The previous history of the pain along with jaundice also suggests about the recurrent biliary episodes which were significantly higher in the late group, p values of all the presenting symptoms in both the groups showed that fever and nausea, vomiting was significantly higher in the Early group while, clay-coloured stools and jaundice were significantly higher in the late group.

Laboratory parameters

In the current study we assessed the preoperative and postoperative LFT and serum amylase & serum lipase reports of early and late groups. It was observed that there was significant improvement in the preoperative to postoperative values of both the groups.

Laparoscopic techniques

In the present study we observed that majority of patients had laparoscopic cholecystectomy (LC). However, due to difficult dissection and dense adhesions Subtotal Cholecystectomy was performed in 4 (10.53%) of the Late group study subjects. The p value for the same was 0.040 which is statistically significant. Also majority of the study subjects were managed using laparoscopic approach (94.74% of the early & 92.11% of the late group), while 5.26% of the early group & 7.89% of the late group with laparoscopic converted to open approach due to confusing anatomy and dense adhesions and excessive intraoperative difficulties. The p value of which is 0.644 which is statistically not significant.

Duration of surgery

In the present study we compared the duration of surgery in both the groups. We observed that mean duration of the Surgery was significantly higher in the late group (82.10 \pm 6.93) as compared to the early group (71.84 \pm 9.47). The p value for the same was <0.0001 suggesting to be highly significant.

Intraoperative findings/complications

We compared the intraoperative findings and complications reported among the study subjects in early & late group. Bleeding among 8% of study subjects of the Early group while that in the study subjects of late group was 47.37%. The p value on comparison was 0.029. It was observed that bulky pancreas was found among 44.74% study subjects of early group which was found to be highly statistically significant when compared to the late group. The late group study subjects intraoperatively showed higher percentage of adhesions, fibrosed gall bladder and empyema gall bladder, the p

value of the same when compared to early group subjects, was found to be statistically significant. Difficult dissection was found in 15.79% of the early group subjects and in 18.42% of the late group subjects. The p value for the same was found to be 1.000.

Postoperative complications

We observed 18.42% study subjects of late group developed postop atelectasis compared to none among the early group. Fever & postoperative increased pain in abdomen were other complications which were statistically significant and higher occurrence in the Late group as compared to the early group. One patient who was among the late group, experienced biliary leak while another one from late group developed postoperative bleeding which was significantly due to dense adhesions & difficult dissection & was controlled after some medical measures.

Hospital stay

In the present study we compared the hospital stay among the study subjects in early & delayed group. We observed that mean duration of hospital stays for early group study subjects (7.55 ± 2.77) was significantly lower as compared to the Late group study subjects (15.39 ± 6.74). The p value for the same was <0.001 which is statistically significant. We also observed that majority of the study subjects had hospital stay in the 10-20 days duration in both early (52.63%) & late (50%) group.

Follow up period

In the current study we assessed the follow up period among the study subjects. We observed that mean duration of follow up was 13.05 ± 8.70 months for the Study subjects in the Early Group while it was 11.97 ± 8.82 for the Study subjects in the Delayed group. This data was not found significant on comparison.

Table 2: Presenting complaints.

Complaints	Early		Late		P value
	N	%	N	%	
Abdomen pain	38	100	38	100	1.000, NS
Fever	20	52.63	9	23.66	0.017, S
Nausea/vomiting	21	55.26	9	23.68	0.009, HS
Clay colored stool	1	2.63	11	28.95	0.003, HS
Jaundice	2	5.26	13	36.11	0.001, HS
Previous episode of pain abdomen	3	7.89	38	100	<0.001 , HS
Recurrent biliary episode (C/o Jaundice+ previous h/o pain in abdomen)	0	0	13	36.11	<0.001 , HS

Table 3: Comparison of pre and post-operative investigations.

Laboratory parameters	Early		Late		
	Mean	SD	Mean	SD	
Total bilirubin	Pre-Op	1.06	0.65	2.08	2.10
	Post-Op	0.66	00.15	0.65	0.13
	P value	<0.0001 , HS		0.0001, HS	
ALP	Pre-Op	184.34	67.18	193.02	71.32
	Post-Op	113.10	17.40	109.76	23.83
	P value	<0.0001 , HS		<0.0001 , HS	
AST	Pre-Op	57.55	19.29	51.34	21.92
	Post-Op	42.47	27.30	30.76	15.58
	P value	0.0001, HS		<0.0001 , HS	
ALT	Pre-Op	42.07	16.28	41.81	23.26
	Post-Op	33.65	17.98	27.23	2.73
	P value	0.0047, HS		0.0024, HS	
Lipase	Pre-Op	539.26	89.02	538.02	139.26
	Post-Op	91.52	16.86	92.86	20.25
	P value	<0.0001 , HS		<0.0001 , HS	
Amylase	Pre-Op	563.97	71.81	549.60	140.91
	Post-Op	93.44	13.60	89.55	23.51
	P value	<0.0001 , HS		<0.0001 , HS	

Table 4: Laparoscopic techniques used in early and late stages.

Laparoscopic cholecystectomy technique used	Early		Late		P value
	N	%	N	%	
Total cholecystectomy	38	100	34	89.47	Chi-Square=4.222, df=1,
Subtotal cholecystectomy	0	0	4	10.53	p=0.040, S
Laparoscopic converted to open approach	2	5.26	3	7.89	Chi-Square=0.2141, df=1,
Laparoscopic approach	36	94.74	35	92.11	p=0.644, NS

Table 5: Comparison of duration of surgery (minutes) in early and late cases.

Duration of surgery (minutes)	Early		Late		P value
	N	%	N	%	
60-75	31	81.56	7	18.42	
76-90	5	13.16	29	76.32	Chi-Square=32.099, df=1,
91-105	2	5.26	2	5.26	p<0.001, HS
Mean duration	71.84 ± 9.47		82.10 ± 6.93		p<0.0001, HS

Table 6: Intra-operative complications in early and late.

Intra-operative findings/complications	Early		Late		P value
	N	%	N	%	
Difficult dissection	6	15.79	7	18.42	1.000, NS
Intraop bleeding	8	21.05	18	47.37	0.029, S
Bulky pancreas	17	44.74	0	0	<0.001, HS
Distended GB	11	28.95	6	15.79	0.271, NS
Dense adhesions	8	21.05	20	52.63	<0.005, HS
Fibrosed GB	0	0	15	39.47	<0.001, HS
Empyema of GB	0	0	6	15.79	0.025, S
Total	50	18.79	72	27.06	0.17, NS

Table 7: Post-operative complications in early and late.

Complications	Early		Late		P value
	N	%	N	%	
Atelectasis	0	0	7	18.42	0.012, S
Fever	10	26.32	30	78.95	<0.001, HS
Pain in abdomen	5	13.16	17	44.47	0.005, HS
Bleeding (immediate)	0	0	1	2.63	1.000, NS
Cystic duct blowout biliary leak	0	0	1	2.63	1.000, NS
Sub hepatic collection	0	0	0	0	-
Surgical site wound infection	0	0	0	0	-
Postoperative ileus	0	0	0	0	-
Postoperative need for readmission	0	0	1	2.63	1.000, NS

Table 8: Hospital stay in days in early and late.

Hospital stay (days)	Early		Late		P value
	N	%	N	%	
<7	17	44.74	4	14.29	
10-20	20	52.63	14	50.00	Chi-Square=15.3063, df=2,
20-30	1	2.63	10	35.71	p<0.001, HS
Mean hospital stay	7.55±2.77		15.39±6.74		<0.0001, HS

Table 9: Follow up period (months) in early and late.

Follow up (months)	Early		Late		P value
	N	%	N	%	
<10	13	34.21	17	44.71	
10-20	17	44.74	14	36.84	Chi-Square=0.8903, df=2, p=0.636, NS
20-30	8	21.05	7	18.42	
Mean follow up	13.05±8.70		11.97±8.82		0.5932, NS

DISCUSSION

Historically, the symptomatic management of gallstone pancreatitis involved the delay of a cholecystectomy until the normalization of laboratory values and the resolution of abdominal pain. Ranson's earlier articles concluded that "definitive correction of cholelithiasis should usually be carried out as soon as evidence of acute pancreatitis has resolved" to avoid exacerbating the severity or recurrence of disease. With the introduction of laparoscopic surgery patients may be better served with earlier intervention. The early cholecystectomy can also be referred to as "hot cholecystectomy".¹¹ More recently, in the era of LC, several studies have shown that delaying surgery in patients with mild pancreatitis may be unnecessary. In study by Taylor and Wong 46 patients had earlier LC, done when serum amylase level began to decrease and abdominal pain began to lessen, resulted in a significant decrease in the length of hospital stay, from 4.7 to 3.5 days, without an increase in complication rates (10% vs. 11%; p=0.12).¹² In our study, we analysed 76 subjects where, the age doesn't affect the outcome the timing of LC in mild to moderate Acute biliary pancreatitis. The gender distribution was similar on comparison. Gender doesn't affect the outcome by timing the LC. Male gender as an isolated risk factor has no impact on the outcomes of LC. Gender affects the duration of surgery because more time is required to complete LC in men than in women. Larger-scale studies may provide a different answer and disclose the factors responsible for variations in the length of surgery between the 2 genders and its impact on perioperative morbidity.¹³ But our study differs in this regard and does not show any correlation between gender and outcome by timing the LC in mild to moderate acute biliary pancreatitis.

The ERCP findings in total 13 out of 76 patients, observed that 2.63% of the Study Subjects from Early group were stented while 31.58 % of the study subjects from the late group were stented. One study subject in the late group who was stented, had history of stent blockade and was re-stented after the recurrent biliary attack. Two of the studies mentioned in the following table show that the ERCP and stenting rate is significantly higher amongst the Late group while others indicate higher similar rate which is statistically not significant.¹⁴

Recurrent biliary events

Recurrent biliary events may present as recurrent pancreatitis, biliary colic or cholecystitis or even choledocholithiasis. Cholecystectomy prevents these biliary events in future. Previously it was thought that early cholecystectomy may not have good results due to peripancreatic oedema and operative difficulty and might lead to increase in peri & postoperative morbidity.

This was later found out to be incorrect due to development and expertise in the laparoscopic technique of cholecystectomy. In our study we found that study subjects with recurrent biliary events were 36.11% in late group and there were no recurrent biliary events found in early group subjects. The p value of this data was <0.001 which was statistically significant. This was also comparable to the other studies mentioning higher recurrent biliary events in the late cholecystectomy group. This suggests that late group study subjects shown significantly higher rate of recurrent biliary events. So, we can state that, Early LC prevents or minimises recurrent biliary events in mild to moderate acute biliary pancreatitis.¹⁵

Perioperative complications

The perioperative complications encountered during LC were intraoperative bleeding, hypotension, difficult dissection, dense adhesions, bulky pancreas, peri-Gall bladder or peripancreatic oedema, bile duct injury, bile leak. All these complications lead to increase in intraoperative time or conversion of laparoscopic approach to open or even in some cases inefficient removal of gall bladder leading to subtotal cholecystectomy.

In some of the early group subjects pancreas were bulky with peripancreatic oedema which led to intraoperative bleeding & difficult dissection in some cases. However, many of the late group subjects had dense adhesions, fibrosed gall bladder, in some empyema of gall bladder. All these occurred due to recurrent biliary attacks and bile stasis. Comparing it with other similar studies, the incidence of perioperative complications encountered during Cholecystectomy is comparable to our study. The p value of our study is 0.17 which is statistically insignificant. We may assume that early LC does not

significantly increase the intraoperative complications in mild to moderate acute biliary pancreatitis.^{16,17}

Conversion to open cholecystectomy

The complications and difficulty during LC led to increase in the intraoperative time & conversion of LC into open procedure. Complications encountered during LC were Intraoperative bleeding, hypotension, difficult dissection, dense adhesions, bulky pancreas, peri-gall bladder or peripancreatic oedema, bile duct injury, bile leak. In this study, we observed that 5.26% of the early group subjects & 7.89% of the late group subjects were managed with laparoscopic converted to open approach. The p value of the same was 0.644 which was statistically not significant. It suggests that the early LC does not significantly affect the conversion rate of laparoscopic to open cholecystectomy in mild to moderate acute biliary pancreatitis.¹⁸⁻²⁰

Duration of surgery

The duration of surgery was calculated from the insertion of the first port to closure of skin incision. Mean duration of surgery was significantly higher in the late group (82.10 ± 6.93) as compared to the early group (71.84 ± 9.47). The p value for the same was <0.0001 suggesting to be highly significant. This may be due to dense adhesions in the late group with gall bladder related complications & recurrent biliary events complicating the biliary structures more. The late intervention led to more frequent attacks and also the patients presented usually late. Compared to the similar data our study has comparable data with higher duration in the late group.^{19,20}

Postoperative complications

The postoperative complications after the LC include atelectasis, fever, bleeding, discharge at operative site, increased drain output, biliary leak, pain at operative site or in the abdomen elsewhere, SSI, postoperative ileus, sub hepatic collection, recurrence of biliary events including pancreatitis, biliary colic etc. All these complications may need readmission after discharge. Postoperative complications were much higher in the late group (36.84%) as compared to the early group (84.21%). The p value for the same data is <0.0001 . As we compare the literature, we find comparable with higher postoperative complications in the late group in our study. This suggests that, early LC minimises postoperative complications significantly as compared to the late LC in mild to moderate pancreatitis.²¹

Hospital stay

This hospital stay duration can be in the index admission or accumulated hospital stay duration including index as well as previous admissions if any. The patients in the late group may need recurrent admissions so cumulative

hospital days are increased. Also, due to higher perioperative & postoperative complications, the Late group subjects had higher stay duration in the index admission as well. It was found that mean duration of hospital stays for early group (7.55 ± 2.77) was significantly lower as compared to the Late group study subjects (15.39 ± 6.74). The p value for the same was <0.001 which is statistically significant. This data was comparable to the similar data of other studies & literature, indicating patient in late group stays in the hospital are significantly higher as compared to the early group suggesting early LC minimises the hospital stay in the patients of mild to moderate acute biliary pancreatitis.²²

Limitations

This was a hospital based longitudinal comparative study. A larger sample size in this study would have been more ideal for the statistical significance. The surgical procedures performed in this study were undertaken by different surgical teams. The inability of having a single surgeon in all procedures increases bias in operative data and results. Though the results may reflect close to that of cholecystectomy procedures in daily practice which are usually performed mostly by general surgeons. However, all this should not affect analysis as the aim of the study is to compare the results between early vs late LC groups.

CONCLUSION

The timing of cholecystectomy early or late is unaffected by age, gender of the subject, while early LC significantly reduces or minimises the risk of recurrent biliary events in mild to moderate acute biliary pancreatitis. Early LC does not significantly increase intraoperative complications in mild to moderate acute biliary pancreatitis. Also it does not affect the conversion rate of laparoscopic to open cholecystectomy in mild to moderate acute biliary pancreatitis. Early LC significantly reduces duration of surgery in mild to moderate acute biliary pancreatitis as compared to the late LC. Early LC minimises postoperative complications significantly as compared to the late LC in mild to moderate pancreatitis while early procedure minimises the total duration of hospital stay in the patients of mild to moderate acute biliary pancreatitis.

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